K022891

# THE BREATHE EZ

FEB 1 9 2003

D&S Redhage
5901 Vedder Road.
New Haven, MO 63068

**Non-Confidential Summary of Safety and Effectiveness**
Page 1 or 3
August 19, 2002

The Breathe EZ
5901 Vedder Road
New Haven, MO 63068

Telephone – (573) 237-3714

| | |
|---|---|
| **Official Contact:** | Daniel J. Redhage, Designer |
| **Proprietary or Trade Name:** | The Breathe EZ |
| **Common/Usual Name:** | Oral Appliance: anti-snoring/grinding |
| **Device Classification Name:** | Anti-snoring device |
| **Predicated Devices:** | Snore-Ezzer, LLC – K991948<br>Marketing Technologies, Inc. – K963063<br>Nellcor Puritan Bennett Inc. – K962516<br>Dr. Kieth Thornton – K972061 |

**Device Description:**

The Breathe EZ Anti-Snoring/Anti-Grinding Device is composed of:

- An oval plate fitted in front of and between the upper and lower teeth and gums.
- A port to facilitate normal breathing

**Intended Use:**

| | |
|---|---|
| Indicated Use: | The Breathe EZ Anti-Snoring Device is intended to reduce or alleviate snoring and to prevent bruxing, clenching and grinding of the teeth while sleeping. |
| Target Population: | Adult patients |
| Environment of Use: | Home and sleep laboratories |

## Non-Confidential Summary of Safety and Effectiveness (continued)

Page 2 or 3

August 19, 2002

### Comparison to Predicate Devices:

| Attribute | The Breathe EZ | Dr. B's Mouthpiece K991948 | Marketing T. I K963063 | Nellcor P.B. K972061 |
|---|---|---|---|---|
| **Use:** | | | | |
| Intended as an intraoral device | Yes | Yes | Yes | Yes |
| Intended to reduce or help alleviate snoring | Yes | Yes | Yes | Yes |
| Indicated for use with persons who snore | Yes | Yes | Yes | Yes |
| Indicated for single user<br>Multi-use | Yes | Yes | Yes | Yes |
| Indicated for use at home or sleep laboratories | Yes | Yes | Yes | Yes |
| **Design:** | | | | |
| Heat sensitive impressible material for fitting to teeth | Yes | Yes | Yes | Yes |
| Custom fit for each user | Yes | Yes | Yes | Yes |
| Can be adjusted or refit | Yes | Yes | Yes | Yes |
| Placed in users mouth each evening | Yes | Yes | Yes | Yes |
| Cleaned daily | Yes | Yes | Yes | Yes |
| Easily removed from mouth | Yes | Yes | Yes | Yes |
| Permits user to breath through mouth | Yes | Yes | Yes | Yes |
| Prevents grinding of teeth | Yes | Yes | Yes | Yes |

## Non-Confidential Summary of Safety and Effectiveness (continued)



August 19, 2002

**Comparison to Predicate Devices**:

| Attribute | The Breathe EZ | Dr. B's Mouthpiece K991948 | Marketing T. I K963063 | Nellcor P.B. K972061 |
|---|---|---|---|---|
| **Materials:** | | | | |
| Heat sensitive impression material | Yes | Yes | Yes | Yes |
| Non-Sterile | Yes | Yes | Yes | Yes |

### Differences Between Other Legally Marketed Predicated Devices

The difference between the intended device and predicates is only the design of the device. The predicate Dr. B's Mouthpiece is very similar in every aspect except that The Breathe EZ has an anti-tongue and lip obstruction component consisting of one port, (tube) that provides an open airway regardless of the position of the tongue and lips.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 1 9 2003

Mr. Daniel J. Redhage
President
D & S Redhage
5901 Vedder Road
New Haven, Missouri 63068

Re: K022891
Trade/Device Name: The Breathe EZ Anti-Snoring Device
Regulation Number: 872.5570
Regulation Name: Anti-Snoring Device
Regulatory Class: II
Product Code: LRK
Dated: December 20, 2002
Received: December 27, 2002

Dear Mr. Redhage:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Susan Runner

Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Page_____of_____

510(k) Number (if known):_____

Device Name: The Breathe EZ anti-snoring device

Indications for Use:

The Breath EZ Anti-Snoring Device is intended to reduce or alleviate snoring by maintaining an open airway and to prevent bruxing, clenching and grinding of the teeth while sleeping.

PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Ken Mulay for MSR
(Division Sign-Off)
Division of Dental, Infection Control,
And Genereal Hospital Devices

510(k) Number K022891

Prescription Use X OR Over-The-Counter-Use_____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)